INdiana Scheduled Prescription Electronic Collection & Tracking

INSPECT PROGRAM

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Indiana Scheduled Prescription Electronic Collection and Tracking

Pharmacies of Indiana:

This information packet serves to inform you of some changes that are taking place with our INSTEP (Indiana Schedule Two Electronic Program). At present, each time a schedule II controlled substance is dispensed, the dispenser is required to submit to the central repository for controlled substances data the following information:

(A) The recipient's name.
(B) The recipient's or the recipient representative's identification number.
(C) The recipient's date of birth.
(D) The national drug code number of the controlled substance dispensed.
(E) The date the controlled substance is dispensed.
(F) The quantity of the controlled substance dispensed.
(G) The number of days of supply dispensed.
(H) The dispenser's United States Drug Enforcement Agency registration number.
(I) The prescriber's United States Drug Enforcement Agency registration number.
(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

For the past several years, dispensers have sent this information to Atlantic Associates, which in turn has provided the information to the Controlled Substances Advisory Committee (CSAC). In January, 2004, CSAC adopted a rule that requires pharmacies to submit the *same information* for schedules II, III, IV and V.

Effective January 1, 2005, **each time a schedule II, III, IV or V** controlled substance is dispensed, the dispenser will be required to collect the following information:

(A) The recipient's name.
(B) The recipient's or the recipient representative's identification number.
(C) The recipient's date of birth.
(D) The national drug code number of the controlled substance dispensed.
(E) The date the controlled substance is dispensed.
(F) The quantity of the controlled substance dispensed.
(G) The number of days of supply dispensed.
(H) The dispenser's United States Drug Enforcement Agency registration number.
(I) The prescriber's United States Drug Enforcement Agency registration number.
(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

This data collection is no different than the information dispensers were collecting for schedule II controlled substances. The only change is that dispensers are now collecting this information for schedule II, III, IV, and V controlled substances.

In accordance with IC 35-48-7-8, the above information is required to be submitted within **15 days after the date on which the controlled substance is dispensed.** In an effort to streamline the reporting process, CSAC will begin collecting the data. **The last data transmission that dispensers should send to Atlantic Associates is December 31, 2004. After that date, Atlantic cannot accept your data.**

In order to provide dispensers with an appropriate amount of time to begin collecting the data for the additional schedules, CSAC will not begin accepting the data from dispensers until February. However, dispensers must be ready to report the data to CSAC by February 1, 2005.

In accordance with IC 35-48-7-8, a dispenser shall transmit the required information by one of the following methods:

1. an electronic device compatible with the receiving device of the central repository,
2. a computer diskette,
3. a magnetic tape, or
4. a pharmacy universal claim form that meets specifications by the advisory committee.

The specifications for the available data submission methods are outlined below:

DATA SUBMISSION OPTIONS

1. **Pharmacy Upload**

   This is a new service offered by CSAC. Our software system gives dispensers the ability to upload their data on a secure website, which utilizes 128-bit encryption. The submitted file must be in ASAP r.5/95 format (as shown on pages 7-10). The file name should be the username, (which will be mailed to you and will likely be your pharmacy license number) followed by the date of submission and followed by **.DAT**. Therefore, if your pharmacy license number is 60000001A and you are submitting on March 1, 2005, the file would look like this: 60000001A030105.dat.

   Please inform your software vendors that you will need to be able to upload your data in the ASAP r.5/95 format as a .DAT file. (This is the same format that dispensers have been submitting to Atlantic Associates.)

   Individual pharmacies will receive information about this new service as well as a username, password and website for access.

   This new data submission method is the only method that has the security infrastructure to protect the patient's personal health information that you are submitting to the CSAC.

   Additionally, dispensers must be able to access CSAC's secure website. This will require an internet connection either in the pharmacy, **or** at the location that is responsible for transmitting data (i.e. a main office or corporate office of the pharmacy).

2. **CD-Rom, CD-R, CD-RW, or 3-1/2"diskette**

   Data must be submitted in the ASAP r.5/95 format.

   The file name should include the pharmacy NABP number, followed by .DAT

These media forms must be mailed to:

Controlled Substances Advisory Committee
ATTN: INSPECT Program
402 West Washington Street, Room W 066
Indianapolis, IN 46204

3. **Magnetic Tape**
   Data may be submitted in the ASAP r.5/95 format (ASCII or EBCDIC) on a DAT-72 36/72GB tape cartridge.

   External label must contain: NABP Number and Date of Submission

   Magnetic Tapes must be mailed to:

   Controlled Substances Advisory Committee
   ATTN: INSPECT Program
   402 West Washington Street, Room W 066
   Indianapolis, IN 46204

4. **Universal Claim Form (or other approved paper reports)**
   A dispenser who does not have an automated record keeping system capable of producing an electronic report in a format described above, may submit prescription information on the industry standard Universal Claim Forms to:

   Controlled Substances Advisory Committee
   ATTN: INSPECT Program
   402 West Washington Street, Room W 066
   Indianapolis, IN 46204

Chain Pharmacies and Community Pharmacies with multiple facilities may submit one data transmission on behalf of all of their facilities. In fact, CSAC **prefers** that chain pharmacies and community pharmacies with multiple facilities submit one transmission with the data for all of their facilities. They may do so utilizing **any of the data submission methods described above**. If they wish to do so, they must appoint one point of contact for all of their data submissions. This individual should complete the "Application for Mass Data Submission" (attached). **Prior to submitting the application, all pharmacies should check with their software vendor to see if they are capable of reporting via our new pharmacy upload service, as this method is far more secure, accessible and efficient.**

REJECTION

The entire data file will be rejected if it does not meet the requirements specified. The submitter will be notified, via email or in writing, of the reason for failure. In the case of diskette, CD Rom/CD-R/CD-RW and magnetic tape, the media will be immediately returned.

THE PROGRAM IMPLEMENTATION SCHEDULE

Initial Data Collection Period	January 1, 2005-January 31, 2005
Deadline for being able to report	February 1, 2005*
Subsequent Reporting	Within 15 days of dispensing (by the 1st and 16th of each month)

*** Pharmacies will receive the official deadline for reporting, a username, password and the secure website address to upload their data at least 10 days prior to the official deadline. Dispensers must be capable of reporting using the methods outlined above by February 1, 2005.**

SUMMARY OF CHANGES:

- Transmissions to Atlantic Associates must cease by December 31, 2004.
- Starting January 1, 2005 dispensers will collect the required prescription information from **Schedules II, III, IV and V**.
- Information will be reported directly to CSAC.
- Dispensers must be able to report by February 1, 2005.
- After the initial reporting, all transactions must be **submitted within 15 days (twice monthly)** of the date of dispensing.
- Information can be uploaded on a secure website, via our pharmacy upload service. This new option is the most secure and efficient method for data transmission.
- **The new system also provides pharmacies with the ability to post messages regarding suspicious activities or robberies in their region of the State of Indiana.**
- **Additionally, this website will also give pharmacies the ability to review legislative and regulatory updates as well as other news from the Board.**

ASSISTANCE AND SUPPORT:

1. The staff of CSAC is available to provide assistance and information to individual pharmacies, chain pharmacies, software vendors, and other entities required to submit data. Technical support is available to meet the program requirements.

2. The State of Indiana will act as the final interpreter of regulations.

3. Individual pharmacies are advised to contact their software vendor. Inform your software vendor that you must be able to upload a ".dat" file (in the ASAP r.5/95 format) to a secure website. This is the same file they should be creating for you to transmit to Atlantic Associates presently. The only change is that you will upload through a secure website. If software vendors have questions, they should contact Joshua M. Bolin, directly at jbolin@hpb.in.gov.

4. **Chain Pharmacies must await information from their individual corporate offices as to how they should proceed with making changes to the existing system.** Corporate offices and their software vendors should contact Joshua M. Bolin, directly at jbolin@hpb.in.gov.

5. Training regarding changes to the reporting requirements, as well as the new reporting options will be held on December 9, 2004 at 1:30pm, at Health Professions Bureau Conference Center, Room W064, Indiana Government Center South, 402 West Washington Street, Indianapolis, IN 46204. Please RSVP to ded@hpb.in.gov and include "Pharmacy Reporting Training" as the subject line.

6. Onsite trainings may be request by appointment by emailing ded@hpb.in.gov.

COMMON QUESTIONS AND ANSWERS

1. **WHAT IF THE PHARMACY/DISPENSER DID NOT FILL ANY CONTROLLED SUBSTANCE PRESCRIPTIONS IN THE REPORTING PERIOD?**
   Please complete and submit (via email, mail or fax) the Program Transmittal Form indicating "ZERO" (0) Controlled Substance prescriptions filled and specify the month reporting.

2. **ARE NURSING HOME PRESCRIPTIONS REQUIRED TO BE REPORTED THROUGH THE PROGRAM?**
   A person who administers or dispenses a controlled substance ordered for a bona fide patient in a facility licensed under IC 16-28 is exempt.

3. **ARE HOSPITAL PRESCRIPTIONS REQUIRED TO BE REPORTED THROUGH THE PROGRAM?**
   Type II pharmacies (as defined in IC 25-26-13-17) operated by a hospital licensed under IC 16-21 are exempt.

4. **HOW ARE COMPOUND PRESCRIPTIONS TO BE RECORDED?**
   Prescriptions compounded by the pharmacist and containing a controlled substance must be reported.

   The NDC number of the controlled substance ingredient must appear in the NDC field and the actual metric quantity of the controlled substance used in the compounding is reported in the quantity field.

   If more than one controlled substance is used, the total net of all controlled substance ingredients is reported as the quantity and the NDC number is reported as eleven "9"s (99999999999).

5. **WHAT DATA IS MANDATORY?**
   The State of Indiana requires that each SCHEDULE II, III, IV and V prescription submitted contain the following data:
   1. The recipient's name.

2. The recipient's or the recipient representative's identification number.
3. The recipient's date of birth.
4. The national drug code number of the controlled substance dispensed.
5. The date the controlled substance is dispensed.
6. The quantity of the controlled substance dispensed.
7. The number of days of supply dispensed.
8. The dispenser's United States Drug Enforcement Agency registration number. (NABP #)
9. The prescriber's United States Drug Enforcement Agency registration number.
10. An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

6. IN WHAT FORMAT MUST I SUBMIT MY DATA?

The format must include the following criteria:

1. Fixed length ASCII text files with one record (line) per prescription.
2. Carriage return and a line feed at the end of each record.
3. Each fixed length record in the file should follow the following layout:

State of Indiana - ASAP R.5/95 Telecommunications Format for Controlled Substances

Field Name	Field Format	Field Length	Positions
**Identifier	A/N	3	001 - 003
Bin	N	6	004 - 009
Version Number	N	2	010 - 011
Transaction Code	N	2	012 - 013
**Pharmacy NABP #	A/N	12	014 - 025
**Customer ID Number	A/N	20	026 - 045
Zip Code	A/N	3	046 - 048
**Birth Date	N	8	049 - 056
Sex Code	N	1	057 - 057
**Date Filled N	8		058 - 065
**Rx Number	N	7	066 - 072
New - Refill Code	N	2	073 - 074
**Metric Quantity	N	5	075 - 079
**Days Supply	N	3	080 - 082
Compound Code	N	1	083 - 083
**NDC Number	N	11	084 - 094
**Prescriber DEA Number	A/N	10	095 - 104
DEA Suffix	A/N	4	105 - 108
Date Rx Written	N	8	109 - 116
Number of Refills Authorized	N	2	117 - 118
Rx Origin Code	N	1	119 - 119
Customer Location	N	2	120 - 121
Diagnosis Code	A/N	7	122 - 128
Alternate Prescriber #	A/N	10	129 - 138

**Patient Last Name	A/N	15	139 - 153
**Patient First Name	A/N	15	154 - 168
**Patient Street Address	A/N	30	169 - 198
**Patient State	A/N	2	199 - 200
**Patient Zip Code (Extended)	A/N	9	201 - 209
Triplicate Serial Number	A/N	12	210 - 221
Filler	A/N	1	222

NOTE: All **A/N** fields must be left justified, right blank filled, and all **N** fields are right justified, left zero filled.

**** Required Field (applicable to the State of Indiana).**

State of Indiana / ASAP R.5/95 Telecommunications Format Field Definitions

Field Name	Definition	Values/ Comments
Identifier		①
BIN		②
Version Number		②
Transaction Code		②
Pharmacy Number	NCPDP/NABP	①
Customer ID Number	Customer Identification Number.	①
Zip Code	3 digit US Postal Code identifying the state code	②
Birth Date	Customer's birth date	① - YYYYMMDD
Sex Code	Sex / Gender of the patient	②1=Male 2=Female 3=Animal
Date Filled	Date the prescription was filled	① - YYYYMMDD

Rx #	Prescription number assigned by the pharmacy	①
New-Refill Code	Code indicating whether the prescription is new or refill	②
Metric Quantity	Number of metric units of drug being dispensed	①
Days Supply	Estimated number of days the prescription will last	①
Compound Code	Code indicating whether or not the prescription is a compound medication	②
NDC Number	National Drug Code of the drug dispensed	① - (5-4-2) format
Prescriber ID	DEA # of the prescribing physician	①
DEA Suffix	DEA Suffix	②
Date Rx Written	Date the Rx was written	② **YYYYMMDD**
Number of Refills Authorized	Number of refills authorized by Prescriber	②
Rx Origin Code	Code indicating the origin of the prescription	②
Customer Location	Code indicating location of patient (customer)	②
Diagnosis Code	ICD-9 or CPT code provided by Prescriber	②
Alternate Prescriber	State license number or HIN. To be included if DEA number field is for an institution rather than the prescriber.	②
Patient Last Name	Patient Last Name	①
Patient First Name	Includes middle initial and suffix	①
Patient Address	Street or PO Box #	①
Patient State	Standard 2-digit State abbreviation (example: VA).	①

Patient Zip Code	Full zip code (including 4-digit suffix if available).	①
Triplicate Serial #	# Assigned to triplicate Rx document by States with triplicate programs.	②
Filler	Filler	②

①. Required Field for Indiana Controlled Substance reporting.
②. Optional field for Indiana Controlled Substance reporting.

7. FUTURE UPDATES

CSAC's staff will mail the following information in the coming months:

1. The official deadline for reporting.
2. Username and password.
3. Secure website address.
4. Other updates regarding changes and upgrades to the system